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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,610

04/27/2007

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ANITUA 6

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1444 7590 01/03/2011

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EXAMINER

LAWSON, MATTHEW JAMES

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

01/03/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,610	Applicant(s) ANITUA, EDUARDO ALDECOA	
	Examiner MATTHEW LAWSON	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorneus et al. (US 5,741,267) in view of Fox (US 6,071,284).

Regarding claims 9-12 Jorneus et al. disclose a milling procedure to be carried out on the bone, cartilage or other patient tissue in order to form a cavity (figures 2-5) of a shape and size that allows it to house an implant or prosthesis (figures 1 and 6) or for other purposes in which a cavity needs to be formed, with the procedure being based on the repeated application of various rotating milling bits (figures 2-6) on the tissue until the required cavity is formed, with the procedure comprising an intermediate phase in which the depth, width and other main features of the cavity are defined (figures 3-4) and an optional countersinking phase (figure 5) in which the mouth of the cavity is widened

Jorneus et al. do not disclose the intermediate, countersinking, or initial phase of bits use being operated at low speeds ranging from between 20 and 80 rpm, nor does Jorneus et al. disclose no use of irrigation solution being applied on the bits, loose tissue particles, or the tissue surrounding the mill hole or cavity during the low speed milling process.

With regard to claim 9, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the method of Jorneus to mill within a range of 20 and 80 rpm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Further, Jorneus et al. fail to disclose the tissue particles displaced or extracted as a result of the milling process are collected for subsequent use in other surgical processes, the recovery of the tissue is not being dependent on the use of suction machines and being based on that the tissue displaced or extracted during the milling process is housed in the milling bits as a result of the retentive design of the bits, so that when the bits is taken out these particles are extracted from it and can be used or stored as appropriate for other surgical uses, and the tissue particles collected during the milling process are mixed with Plasma Rich in Growth Factors or with other biological materials for desirable medical purposes.

Fox discloses the collection of displaced or extracted tissue particles as a result of the milling process and are collected for subsequent use in other surgical processes (figures 3a-3b) the mill bit comprising tissue retention areas between adjacent spiral grooves (column 16, lines 28-40) and being housed in the milling bits as a result of the retentive design of the bits (figures 3a-3b, column 16, lines 28-40), so that when the bits is taken out these particles are extracted from it (via the wiper 130, figures 1, 3a-4a if desire or without wiper) and can be used or stored as appropriate for other surgical

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uses, and the tissue particles collected during the milling process are mixed with Plasma Rich in Growth Factors or with other biological materials for desirable medical purposes (column 10, lines 27-43) to permit collection and subsequent use of the extracted bone particles (column 16, lines 28-40, column 10, lines 27-43).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the method of Jorneus et al. to including collection of collecting the tissue particles displaced or extracted as a result of the milling process for subsequent use in other surgical processes, the recovery not being dependent on the use of suction machines and so that when the bits is taken out these particles are extracted from it and can be used or stored as appropriate for other surgical uses as taught by Fox to better fixate the implant within the milled out surgical site and to permit collection and subsequent use of the extracted bone particles.

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorneus et al. (US 5,741,267) in view of Fox (US6,071,284) in further view of Lorenzi (US 2002/0094508).

Regarding claims 9-12 Jorneus et al. disclose a milling procedure to be carried out on the bone, cartilage or other patient tissue in order to form a cavity (figures 2-5) of a shape and size that allows it to house an implant or prosthesis (figures 1 and 6) or for other purposes in which a cavity needs to be formed, with the procedure being based on the repeated application of various rotating milling bits (figures 2-6) on the tissue until

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the required cavity is formed, with the procedure comprising an intermediate phase in which the depth, width and other main features of the cavity are defined (figures 3-4) and an optional countersinking phase (figure 5) in which the mouth of the cavity is widened

Jorneus et al. do not disclose the intermediate, countersinking, or initial phase of bits use being operated at low speeds ranging from between 20 and 80 rpm, nor does Jorneus et al. disclose no use of irrigation solution being applied on the bits, loose tissue particles, or the tissue surrounding the mill hole or cavity during the low speed milling process.

Lorenzi discloses the use of milling bits being operated at low speeds (less than 200 rpm, ¶33) without the use of irrigation solution (figures 1, and 3) to reduce trauma even further, and further to minimize bone damage and the possibility of a bone fracture when operating on dense bone.

Further, Jorneus et al. fail to disclose the tissue particles displaced or extracted as a result of the milling process are collected for subsequent use in other surgical processes, the recovery of the tissue is not being dependent on the use of suction machines and being based on that the tissue displaced or extracted during the milling process is housed in the milling bits as a result of the retentive design of the bits, so that when the bits is taken out these particles are extracted from it and can be used or stored as appropriate for other surgical uses, and the tissue particles collected during the milling process are mixed with Plasma Rich in Growth Factors or with other

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biological materials for desirable medical purposes.

Fox discloses the collection of displaced or extracted tissue particles as a result of the milling process and are collected for subsequent use in other surgical processes (figures 3a-3b) the mill bit comprising tissue retention areas between adjacent spiral grooves (column 16, lines 28-40) and being housed in the milling bits as a result of the retentive design of the bits (figures 3a-3b, column 16, lines 28-40), so that when the bits is taken out these particles are extracted from it (via the wiper 130, figures 1, 3a-4a if desire or without wiper) and can be used or stored as appropriate for other surgical uses, and the tissue particles collected during the milling process are mixed with Plasma Rich in Growth Factors or with other biological materials for desirable medical purposes (column 10, lines 27-43) to permit collection and subsequent use of the extracted bone particles (column 16, lines 28-40, column 10, lines 27-43).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the method of Jorneus et al. to including collection of collecting the tissue particles displaced or extracted as a result of the milling process for subsequent use in other surgical processes, the recovery not being dependent on the use of suction machines and so that when the bits is taken out these particles are extracted from it and can be used or stored as appropriate for other surgical uses as taught by Fox to better fixate the implant within the milled out surgical site and to permit collection and subsequent use of the extracted bone particles.

Further, it would it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the method of Jorneus et al. to

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operate the mill bits at a low speed between about 20 to 80 rpm without irrigation fluid as taught by Lorenzi to reduce trauma even further, and further to minimize bone damage and the possibility of a bone fracture.

Response to Arguments

Applicant's arguments filed 9th December 2010 have been fully considered but they are not persuasive. The Applicant argues that the rotation of milling bits at a range between about 20 to 80 rpm's is not obvious nor optimal for milling bone, but rather is an optimal for low speed milling when recovery of milling particle is desired and that the results of his findings are unexpected improved results. The examiner respectfully disagrees with this assertion as the applicant has identified an optimal working range for particle recovery which one of ordinary skill in the art would strive to find when performing this procedure. Further, even if the Applicant still considers this limitation to have been found by unexpected results from extensive testing Lorenzi teaches the limitation of low speed milling to reduce trauma to the milled bone.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW LAWSON whose telephone number is (571)270-7375. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MATTHEW LAWSON/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
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